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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,063	02/27/2004	Robert W. Marquis JR.	P50523-C3	7357

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GLAXOSMITHKLINE

Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/789,063

Applicant(s)

MARQUIS ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 15-25 and 34 is/are pending in the application.
4a) Of the above claim(s) 7-11, 13, 19-25 and 34 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6, 15 and 18 is/are rejected.
7) ☒ Claim(s) 16 and 17 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/27/04.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

It is acknowledged that in the reply of 10-03-05, applicants have elected the invention of Group I, species of Example 59, which is 4-[[N^a-(4-pyridinylmethoxycarbonyl)-L-leuciny]amino]-1-(2-pyridylsulphonyl)-3-pyrrolidinone.

Applicant traversed that the compounds of formula (I) “share a common operation, as found in their mechanism of action...; and they share a common effect, which is the inhibition of bone loss.” Applicant further contended that “The compounds, methods of use and processes for preparing the compounds are so connected as to have arisen from a singular research effort.”

Said traversal is not found persuasive because common utility is not sufficient to keep all distinct species in the same invention. In the instant case, formula I does not really have a common special technical feature.

Although method of use and process are arisen from the same research, they have different patentability criteria, and must be considered separately from the compounds. Thus, they require additional search, which imposes a serious burden of searching and examining.

Claims 12, 14, and 26-33 are cancelled.

Claims 1-11, 13, 15-25 and 34 are pending.

Group I was indicated with further restriction, and thus, it is broken down as follows:

Group Ia: Claims 1-6, and 15-18, drawn to compounds of formula I wherein:

- n = 0; A is C(O);

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- R^1 is $R^4-N(R^6)-CH(R^3)-Z-$;
- R^2 is R^5SO_2- ;
- R^5 is pyridinyl or pyridyl;

Pharmaceutical composition thereof; classified in class 514, subclasses 317, 320; also class 546, subclasses 196 and 216.

Group Ib: Claims 1, 7-11, 13 and 15-18, drawn to compounds of formula I with the remaining substituents, and pharmaceutical composition thereof; classified in classes 514, 540, 544, 546 and 548, various subclasses depending on the substituents.

The elected species falls within Group Ia, and thus, only claims **1-6 and 15-18 are considered.**

Non-elected claims: Claims 7-11, 13, 19-25 and 34 are withdrawn from consideration as being drawn to the non-elected subject matter.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-6, 15 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claim 1 has indefinite metes and bounds because it recites the broad limitation of “Het” followed by the narrow limitation of specific rings.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

- b. Claim 1 defines R’ in terms of groups having “Ar” and “Het”, but “Het” and “Ar” have substituents that contain R’. Thus, it is unclear what the scope of R’, “Ar”, and “Het” is.

- c. Claim 5 lacks antecedent basis because it depends on claim 1, but recites substituents that are not recited in claim 1. Note, the “phenyl” and “benzyl” groups in R⁵ of claim 1 are not indicated as can be substituted with *halogen, alkyl, OH, CF₃, etc.*

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Claim Objections

2. Claims 16 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 16 and 17 are free of prior arts because they recite elected species with the combination of *pyrrolidinone* and *pyridinyl-sulfonyl* that is not taught or fairly suggested by the prior art of record.

References cited on PTO-892

3. The cited references only show state of the art. The closest reference is **Greco et. al.** (US 6,538,017 B2). While it teaches *pyrrolidinone* derivatives, it fails to teach the *pyridinyl-sulfonyl* as a substituent on the pyrrolidione ring.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

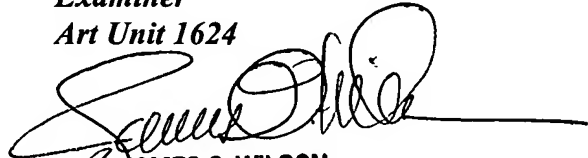
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12-22-05


Tamthom N. Truong
Examiner
Art Unit 1624


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600